IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND, on behalf of itself and all others similarly situated, JOSEPH MACKEN, and COMMISSIONER LINDA A. WATTERS, Plaintiffs, v. ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, L.P., Defendants.	Civ. No. 05-075-SLR (Lead Case)

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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I. NATURE AND STAGE OF THE PROCEEDING

AstraZeneca erects its motion on a fundamental misstatement of Plaintiffs' claim. Urging dismissal on preemption and First Amendment grounds, AstraZeneca asserts that the gravamen of the complaint is the contention that AstraZeneca deceived the U.S. Food and Drug Administration's ("FDA" or the "Agency") into approving Nexium. But Plaintiffs do not challenge the FDA's approval of Nexium. They instead challenge AstraZeneca's promotional activities creating demand for Nexium by claiming – falsely – that Nexium was superior to Prilosec. The complaint identifies Plaintiffs' specific claims of wrongful conduct at ¶ 155(a)-(o), none of which involve the FDA's approval of Nexium.

II. SUMMARY OF ARGUMENT

1. The FDA's approval of Nexium and its labeling means only that the Agency has determined Nexium meets safety and efficacy standards. But the FDA approved Nexium based on tests comparing its efficacy to a placebo. The FDA-approved Nexium label thus does not state that the FDA approved claims that Nexium was superior to Prilosec. Indeed, to the extent the label addresses this issue at all, it indicated that studies showed no superiority of Nexium over Prilosec.

2. The FDA did not review the accuracy of AstraZeneca's promotion of Nexium. In a barrage of messages to physicians and consumers, AstraZeneca stated expressly or by implication that Nexium was superior to Prilosec and compared favorably to Prilosec in clinical trials. These statements were false. No scientific proof exists that Nexium is superior to Prilosec.

3. FDA regulation does not preempt state laws that require drug manufacturers to make truthful claims about their product. FDA-approved drug labeling reflects a minimum disclosure standard for drug safety and efficacy, and drug advertisements are not confined to rote reiterations of the labeling. To the extent

promotional statements fall outside the labeling, they are subject to state tort law, which in such cases strengthens and complements the Food, Drug, and Cosmetic Act's ("FDCA") purposes. Courts therefore uniformly find that the FDCA does not preempt claims like those presented here.

4. Nor does the First Amendment bar this case. First, the Noerr-Pennington doctrine is inapplicable because the complaint does not attack the decision to seek approval for Nexium – it attacks post-approval marketing activity directed at physicians and consumers. Second, the complaint alleges far more than "inherently misleading speech." It alleges false statements and omissions of material fact. Third, Plaintiffs do not propose any corrective disclosure, so AstraZeneca cannot complain that this action seeks to compel commercial speech.

5. Plaintiffs have standing. Plaintiffs alleged that there is a concrete causal connection between the cumulative effects of AstraZeneca's false advertising directed at both physicians and consumers and the injury they suffered, namely, the payment for Nexium, rather than less expensive, therapeutically equivalent alternatives. Third Circuit authority squarely on point confirms standing and Second Circuit authority found standing in a remarkably parallel case involving the marketing of a "new" more expensive drug that was clinically the same as the less expensive older drug.

III. STATEMENT OF FACTS

A. AstraZeneca's Wildly Profitable Prilosec Franchise

Prilosec, which is used to treat heartburn and related conditions, was for many years AstraZeneca's flagship product. Long advertised as the "purple pill," Prilosec was the most widely prescribed and top-selling drug in the world by the year 2000, with

annual sales of $6 billion. ¶¶ 2, 32, 45.[1] By 2000, nearly 40% of the Company's revenue was attributable to sales of that one product.

AstraZeneca's U.S. patent protection for Prilosec was set to expire in 2001, however. As with virtually all blockbuster drugs that go off patent, the Company anticipated that competition from generic manufacturers would cause a substantial reduction of Prilosec sales and a corresponding loss of revenue. ¶¶ 4, 40, 44. In short, a patent-expiration disaster loomed on the horizon. But AstraZeneca saw it coming, so it formed a team of marketers, lawyers and scientists to come up with a way to prevent the impending revenue loss that Prilosec's patent expiration would bring. The group called itself the "Shark Fin Project," the name inspired by the dismal inverted-V shape that the sales chart would take if they did nothing and allowed generic competition to erode Prilosec's market share. ¶¶ 4, 45.

B. The Shark Fin Project's Solution: Nexium

The eventual centerpiece of the Shark Fin Project's strategy was the marketing and promotion of a new heartburn drug, which was given the brand name Nexium. The active ingredient in Prilosec – omeprazole – is what is known as a proton-pump inhibitor ("PPI"); it acts by inhibiting the creation of gastric acid. The active ingredient in Nexium – esomeprazole – also a PPI, is derived from the active ingredient in Prilosec. Whereas the omeprazole molecule has two "mirror image" isomers, called S- and R-enantiomers, esomeprazole is simply the S-enantiomer of the omeprazole molecule. Thus, AstraZeneca patented a "new" clinical compound that is simply Prilosec without the R-enantiomer. Several AstraZeneca executives viewed Nexium as the poorest solution because they knew that Nexium was no better for ordinary heartburn than Prilosec.

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[1] "¶ __" denotes references to paragraphs in Plaintiffs' Consolidated Class Action Complaint (D.I. 20).

Nonetheless, with time running out and no other alternatives, Nexium was the chosen replacement. ¶¶ 2, 46, 71.

C. The Clinical Proof Shows That Nexium and Prilosec Are Comparable But AstraZeneca Promotes Nexium As Better

1. The clinical trials: FDA limits its approval to the issue of whether Nexium is better than a placebo

To gain regulatory approval for Nexium, AstraZeneca needed to and did successfully demonstrate in clinical trials submitted to the FDA that Nexium was more effective than placebo. But seven of the fourteen clinical trials that AstraZeneca conducted compared Nexium and Prilosec head-to-head, *i.e.*, four "efficacy trials" for the treatment of erosive esophagitis and three "supportive trials."[2] ¶ 49.

The FDA approved Nexium for the healing of erosive esophagitis, the maintenance of erosive esophagitis and the treatment of GERD.[3] The FDA did not, however, approve Nexium as a superior product to Prilosec. In fact, the FDA reviewers found that AstraZeneca's comparative clinical studies did "not lead to the conclusion that [Nexium] is superior to [Prilosec] in healing [erosive esophagitis]." ¶¶ 59, 65. The FDA's Medical Review (the "FDA Review") of the Nexium new drug application ("NDA") flatly stated that a claim that Nexium was superior to Prilosec for the healing of erosive esophagitis is "NOT SUPPORTED." ¶ 53 (emphasis in original). Nor was there support for a superiority claim for the treatment of symptomatic GERD. ¶ 67 ("claims of superiority [of Nexium] to omeprazole are – once again – not supported. Neither H40

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[2] Erosive esophagitis is a condition characterized by the erosion of the lining of the esophagus caused by chronic backflow of acid from the stomach through a muscular valve separating the stomach from the esophagus. It is one of the three conditions for which AstraZeneca sought FDA approval for Nexium. The other two indications for which PPIs are approved are the maintenance and healing of erosive esophagitis and the treatment of symptomatic gastroesophogeal reflux disease ("GERD" or "S-GERD"). The backflow of acid is also the cause of what is commonly known as "heartburn" or acid indigestion; stomach acid entering the esophagus causes a burning sensation in the chest and throat. ¶¶ 33, 34, 37.

[3] Def. Request for Judicial Notice, Ex. 1 at p. 23.

[Nexium 40 mg] nor H20 [Nexium 20 mg] could be differentiated from O20 [Prilosec 20 mg]). With respect to the three "supportive trials," the FDA found that "[a]ll three studies failed to demonstrate superiority of [Nexium] over [20 mg of omeprazole]." ¶ 61.

A central premise of Defendants' brief is that, notwithstanding the FDA Review, the FDA resolved its concerns over the Nexium-Prilosec superiority issue, the implication being that the Agency condones AstraZeneca's marketing of Nexium. See Def. RJN Ex. 1 (approved indication at p.23). But the label merely reports on the differences between Prilosec and Nexium; it does not support such superiority claims, either expressly or by implication. For example, the label reports that European symptomatic GERD trials showed "no significant treatment related differences" between Prilosec and Nexium. Def. RJN Ex. 1 at 20. The label notes four clinical studies regarding heartburn resolution and in most instances reprints data showing no statistically significant difference between Nexium and Prilosec users. Def. RJN Ex. 1 (Study 1, Study 2, Study 3). A plain reading of the label does not support AstraZeneca's assertion that the FDA approved by implication that claims that Nexium was superior to Prilosec.

2. No statistically significant evidence suggests that Nexium is superior to Prilosec

To succeed in using Nexium to replace the Prilosec revenue stream, AstraZeneca needed to charge the premium prices that brand-name drugs command and capture a significant share of the market. To do that, the Company needed a compelling promotional message: Nexium is better than Prilosec. AstraZeneca thus undertook the seven additional head-to-head clinical trials to develop data showing that Nexium was, in fact, a better, more effective medication than Prilosec in order to justify AstraZeneca's promotional message. If, however, studies showed that Nexium was ***not*** an improvement over the older drug, there would be no reason for doctors to prescribe it or for endpayors such as Plaintiffs who use or pay for it. ¶ 48.

The FDA's Review confirmed there was no scientific support to claim Nexium superiority over Prilosec. The FDA Review[4] found that the studies demonstrated no superiority of Nexium for healing erosive esophagitis:

> ... a superiority claim of Nexium over omeprazole [Prilosec] is not supported by either the comparison of H20 [Nexium 20 mg] vs. O20 [Prilosec 20 mg] or the comparison of H40 [Nexium 40 mg] vs. H20 [Nexium 20 mg]. [¶ 65.]

There likewise was no superiority for treatment of symptomatic GERD:

> ... claims of superiority [of Nexium] to omeprazole are – once again – not supported. Neither H40 [Nexium 40 mg] nor H20 [Nexium 20 mg] could be differentiated from O20 [Prilosec 20 mg]. [¶ 67.]

The "SUMMARY OF BENEFITS VS RISKS" section of the FDA's Medical Review further demonstrates the FDA's finding that the comparative studies did not establish Nexium's superiority:

> It is important to point out that in order to determine whether one compound is superior to another, these drugs need to be tested at comparable amounts: H20 [Nexium 20 mg] vs. O 20 [Prilosec 20 mg]; H40 [Nexium 40 mg] vs. O 40 [Prilosec 40 mg]. The sponsor's comparisons of H40 to O 20 do not yield valid conclusions about the superiority of H [Nexium] over O [Prilosec], although these comparisons are adequate to demonstrate that [Nexium] is active in the assessed indications. Therefore ***the sponsor's conclusions that [Nexium] has been shown to provide a significant clinical advance over [Prilosec] in the first-line treatment of patients with acid-related disorders is not supported by data***. [¶ 68 (emphasis added).]

The FDA concluded:

> In addition, it is recommended not to allow the sponsor to claim that [Nexium] has any significant clinical advantage over [Prilosec] in the first-line treatment of these acid-related disorders because no data in support of such a claim have been submitted. [¶ 69.]

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[4] Hugo E. Gallo-Torrees, MD, PhD, Medical Team Leader, Medical Review(s), FDA Center for Drug Evaluation and Research, Application Number: 21-153/21-154, September 21, 2000, at 3-6 (see ¶ 64 n.14).

Further, nothing in the final FDA-approved label contradicts this recommendation that Nexium should not be allowed to claim superiority of Nexium over Prilosec.

3. AstraZeneca's false and misleading marketing campaign

AstraZeneca's Nexium marketing campaign was driven, not by what the data actually showed and the FDA approved, but by what the Company needed to say to obtain commercial success. Indeed, AstraZeneca's 2000 Annual Report succinctly describes its overarching marketing theme that Nexium is a more effective successor to Prilosec: "***Nexium is the first PPI to offer significant clinical improvements over [Prilosec]*** in terms of acid control and clinical efficacy, shown in clinical studies involving over 30,000 patients performed across 20 countries. It is expected to establish a new, ***improved treatment standard for the PPI class***." ¶ 89 (emphasis added).

A massive promotional campaign targeting both prescribing physicians and consumers drove home that theme. Nexium became the most heavily advertised pharmaceutical product in the United States. The promotional campaign reportedly cost AstraZeneca a half billion dollars in the year 2001 alone. ¶¶ 7-8, 86, 90.

Defendants built the Nexium campaign around the brand identity already established with Prilosec. The Company had long heavily advertised Prilosec as "the purple pill" to relieve heartburn. AstraZeneca capitalized on that brand identity by marketing Nexium in a way that connected it to, yet differentiated it from, Prilosec, *e.g.*, as the "new" purple pill, "today's" purple pill, the "healing" purple pill, or by stating that relief is "possible with the purple pill called Nexium." ¶¶ 116, 117. Nexium advertisements aimed both to consumers and physicians conveyed the false and misleading message that Nexium is a clinical advance over, and a better drug than Prilosec, which by comparison was ***yesterday's*** purple pill, the ***old*** purple pill, the purple pill with which "healing" and "relief" are ***not*** possible. ¶ 116, 121. *See also, e.g.*, ¶¶ 123, 124 ("We captured the ESSENCE of Prilosec … and created a NEW PPI … Introducing NEXIUM

... the POWERFUL new PPI from the makers of Prilosec"); ¶ 124 ("The POWERFUL new PPI ... NEW Nexium ... from the maker of Prilosec"); ¶ 126 ("The makers of Prilosec ... proudly introduce Nexium Relieve the heartburn. Heal the damage. For many, it's possible with NEXIUM."); ¶ 132 ("Relieve the heartburn Heal the Damage. It's possible with the purple pill called NEXIUM.").[5] Likewise, in sales pitches to doctors, AstraZeneca employees conveyed the false message that Nexium was the first to offer improvements over Prilosec and that Nexium was "improved treatment for the PPI class." ¶ 95.

This marketing campaign paid off. The Company achieved $3.3 billion in Nexium sales within three years of its introduction. ¶ 107.

4. Nexium Is "A Game Being Played" on Payors

In 2003, the administrator of the federal Centers for Medicare and Medicaid Services, Tom Scully, told physicians at a convention of the American Medical Association that they should not prescribe Nexium because Prilosec, which had become available in generic form the previous December, costs less and provides the same level of treatment. Indeed, Mr. Scully scolded doctors, "You should be embarrassed if you prescribed Nexium," because it increases costs with no medical benefits. "The fact is, Nexium is Prilosec," Mr. Scully said. "It is the same drug. It is a mirror compound." Perceptively describing AstraZeneca's scheme, Mr. Scully stated that "Nexium is a game that is being played on the people who pay for the drugs making it one of the most successful launches ever of a new medicine." ¶¶ 14, 106.

[5] Capitalized in advertisements.

IV. ARGUMENT

A. Plaintiffs' Claims Are Actionable Under Delaware's Consumer Fraud Act And Not Preempted by The FDCA Because The FDA Did Not Approve AstraZeneca's Deceptive Statements

1. AstraZeneca's deceptive conduct does not fall within the Delaware Consumer Fraud Act's safe harbor

AstraZeneca tries to jam its deceptive practices into the Delaware Consumer Fraud Act's ("DCFA") safe harbor for conduct specifically authorized by a regulatory agency. AstraZeneca contends that Plaintiffs cannot plead a DCFA violation as a claim because the transactions or actions at issue here are subject to the FDA's regulatory authority as a result of regulations promulgated under the FDCA and, as such, are exempted under 6 Del. Code § 2513(b)(2). But AstraZeneca's conduct is not within the DCFA's safe harbor for several reasons: (i) the FDCA does not affirmatively permit the consumer scam at issue here; and (ii) the promotional representations at issue here are extraneous to Nexium's FDA-approved labeling.

a. The FDA did not explicitly authorize AstraZeneca's marketing scheme

The FDA did not affirmatively authorize marketing of a drug that merely extends the market power of an older drug. The FDA's (and the FDCA's) primary mission is protecting the public's health, not its dollars. Congress created the FDA to "protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696 (1948); *see also United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969); *National Nutritional Foods Asso. v. Kennedy*, 572 F.2d 377, 391 (2d Cir. 1978); *Zenith Labs., Inc. v. Abbott Labs.*, 1996 U.S. Dist. Lexis 22567, at *13 (D.N.J. Aug. 7, 1996). The FDA's core responsibility for pharmaceutical drugs is to ensure that any drug regulated by the FDA is "safe" and "effective" for its intended use. *See* 21 U.S.C. § 393(b)(2); *FDA v.*

Brown & Williamson Tobacco Corp., 529 U.S. 120, 133-34 (2000).[6] The FDA accomplishes this by conditioning approval of any drug on a finding that the drug's "benefits outweigh its risks." 50 Fed. Reg. 7469 (1985); *see also United States v. Rutherford*, 442 U.S. 544, 555 (1979); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. at 133-34.

Under this mandate as public-health protector, the FDA closely regulates drug labeling to assure accurate disclosure relating to safety and efficacy.[7] 21 C.F.R. § 201.5 ("'[a]dequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended'"); *Kordel v. United States*, 335 U.S. 345, 349 (1948) (purpose of drug labeling is to "protect consumers who ... are largely unable to protect themselves in this field"); *McNeilab, Inc. v. Heckler*, 1985 U.S. Dist. Lexis 19169, at *8 (D.D.C. June 5, 1985) ("it is nevertheless clear from the Act that the warnings and directions on a drug's label are the focal point in the FDA's determination of safety and effectiveness for purposes of NDA approval").

Indeed, the FDA regulations cited by AstraZeneca police drug labeling and advertising for safety and efficacy concerns. For example, AstraZeneca discussed the FDA's NDA process, which allows the FDA to assess whether a new drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling. Def. Br. at 6-7 (citing 21 U.S.C. § 314.105(c), 21 U.S.C. § 355(b); 21 C.F.R.

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[6] For example, 21 U.S.C. § 393(b)(2) defines the FDA's "mission" to include "protect[ing] the public health by ensuring that ... drugs are safe and effective" and that "there is reasonable assurance of the safety and effectiveness of devices intended for human use." *See also* 50 Fed. Reg. 7452 (1985) (FDA's mandate is to act "as a public health protector, by keeping off or taking off the market drugs not shown to meet safety and efficacy standards").

[7] A drug's proposed "labeling" includes, *inter alia*, all proposed claims about the drug's risks and benefits, as well as adequate directions for use. *See, e.g.*, 21 U.S.C. § 352(f). Labeling is a term of art that encompasses all written, printed or graphic material "(1) upon any [drug or device] or any of its containers or wrappers, or (2) accompanying such [drug or device]." 21 U.S.C. § 321(k) & (m). *See also Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 55 (D.D.C. 1998).

§ 314.50(c)(2)(i)). A drug's labeling reflects the FDA's assessment of these factors. 21 C.F.R. § 201.57(C), (J).[8]

FDA scrutiny does not encompass the sorts of consumer deceptions at issue here, *i.e.*, promotional misrepresentations of a drug's purported superiority over others:

> The FD & C Act, in contrast, is not focused on the truth or falsity of advertising claims. It requires the FDA to protect the public interest by "[passing] on the safety and efficacy of all new drugs and ... [promulgating] regulations concerning the conditions under which various categories of OTC drugs ... are safe, effective and not misbranded."

Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 230 (3d Cir. 1990). *See also Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993); *Solvay Pharms., Inc. v. Global Pharms.*, 298 F. Supp. 2d 880, 883 (D. Minn. 2004). AstraZeneca thus points to no law, regulation or FDA action – because there is none – establishing that the FDA actually approved AstraZeneca's promotional representations of Nexium's effectiveness relative to Prilosec.

Thus, while the FDA and FDCA do not protect consumer dollars, there are other statutes that do. As courts have noted, consumer-protection laws must possess the flexibility necessary to respond to mankind's boundless creativity to conjure innovative new deceits. *See, e.g., SEC v. Capital Gains Research Bureau, Inc.*, 375 U.S. 180, 194 n.41 (1963); *Holiday Inns v. 800 Reservation*, 86 F.3d 619, 625 (6th Cir. 1996); *Summit Mach. Tool Mfg. Corp. v. Victor CNC Sys.*, 7 F.3d 1434, 1440 (9th Cir. 1993); *Rambus, Inc. v. Infineon Techs. AG*, 304 F. Supp. 2d 812, 818 (E.D. Va. 2004); *In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 325 (S.D.N.Y. 2003). The FDCA is not such a consumer-protection law. Scams foisted on consumers of pharmaceutical drugs plainly are not limited solely to false claims of drug safety or efficacy. Indeed, the Second

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[8] AstraZeneca also cites FDA pre-enforcement warning letters to companies relating to their advertising. Def. Br. at 21 n.16. But these letters concern misrepresentations about drug safety and approved indications, not statements about a drug's purported superiority over competing drugs. *See id.*

Circuit recently considered a prescription-drug scam under a state consumer-protection statute very much like AstraZeneca's here, noting that it did not concern safety and efficacy – the hallmarks of the FDA and FDCA's protective mission:

> Consider, for example, a hypothetical in which a defendant drug company markets a "new," much more expensive drug claiming it is a great advancement (safer, more effective, *etc.* than metformin – the standard diabetes drug) when in fact the company is simply replicating the metformin formula and putting a new label on it. In other words, the only difference between metformin and the "new" drug is the new name and the higher prescription price (paid almost entirely by the insurance company). In that case, the "new" drug would be ***exactly as safe and effective*** as metformin, and thus there could be no injury to any of the insurance company's insured. ***Nevertheless, the insurance companies would be able to claim – precisely as they do here – that the defendants engaged in a scheme to defraud it***, and that the company suffered direct economic losses as a result.

Desiano v. Warner-Lambert Co., 326 F.3d 339, 349-50 (2d Cir. 2003) (emphasis added).[9]

The Third Circuit has also ruled that state laws regulating deceptive drug advertising or promotion do not conflict with the FDCA's labeling requirements designed to protect public health:

> a state law fraud claim based on [the defendant manufacturer's] advertising and promotional activities does not impose a requirement that "is different from, or in addition to" a FDA requirement and "which relates to the safety or effectiveness of the device or to any … requirement applicable to the device under this chapter."

Michael v. Shiley, Inc., 46 F.3d 1316, 1330 (3d Cir. 1995). In *Michael*, the plaintiff's fraudulent-promotion claim did not depend on the defendant's labeling representations, and the claim thus did not conflict with any FDA action. *Id.* at 1331.

Here, as in *Michael* and *Desiano*, Plaintiffs' claims are for economic injury; they stemmed from AstraZeneca's swindle to switch consumers suffering from certain

[9] *Desiano* recognized a right under the New Jersey Consumer Fraud Act to recover from drug companies the amounts that were overpaid due to illegal or deceptive marketing practices.

digestive-acid ailments from its low-margin Prilosec drug to its high-margin Nexium. Further, Plaintiffs do not allege that Nexium was not as safe or effective as indicated in its labeling; nor do they complain about the Nexium labeling itself. The Complaint contains no request that AstraZeneca alter any part of Nexium's labeling or labeling-dependent statements in Nexium advertisements. And thus, no part of Plaintiffs' claims is based on conduct that the FDA affirmatively approved.

b. AstraZeneca's promotional misrepresentations are not derived from the FDA-approved Nexium label and there is no collateral attack on the label

AstraZeneca's promotional scheme is not preempted because the promotional statements at issue are not derived from the FDA-approved labeling for Nexium. As already established, the FDA concluded that Nexium was not more powerful or effective than Prilosec. ¶¶ 50, 53, 55, 57, 59-61, 65, 67-69. The FDA concluded from the studies AstraZeneca submitted for FDA review that "superiority of Nexium over omeprazole was not demonstrated." ¶¶ 14, 50. Indeed, the FDA stated, "[t]here are no studies which demonstrate that [esomeprazole or Nexium] is superior to [omeprazole or Prilosec], clinically or even statistically." ¶ 76. It also expressly rejected AstraZeneca's claim of Nexium superiority over Prilosec. *See supra* at 6.

But the FDA-approved labeling merely summarized test results, without the FDA's conclusions or commentary. See, for example, RJN Ex. 1 at 13-15. Plaintiffs are not claiming that the labeling contains any representation regarding Nexium superiority or strength. Plaintiffs challenge no statement in the FDA-approved labeling for Nexium. AstraZeneca's statements about a collateral attack on the label are simply a distraction – a straw man it sets up to knock down.

AstraZeneca cites *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934 (7th Cir. 2001), to knock down the straw man "collateral attack" argument, but it does nothing to sidetrack Plaintiffs' claims. The cited passage in *Bober* addressed whether a consumer

could state a claim arising from a drug company's answer to his direct question about drug substitutability. The court found that the question and answer narrowly focused on an area closely governed by the FDA's labeling regulations, which prohibit a drug manufacturer from mentioning uses for a drug not approved by the FDA or "supported by sufficient medical evidence." 246 F.3d at 942. The answer strictly adhered to the FDA's approved labeling for the drugs, and thus the Court ruled that FDA regulations "specifically authorized" Glaxo's answer. *Id.* at 942-43.

Here, AstraZeneca's promotional statements were not derived from FDA-approved labeling nor supported by medical evidence. The FDA found that there was no medical support that Nexium is stronger or superior to Prilosec, yet that is precisely the message Plaintiffs allege that AstraZeneca seeks to and does communicate through its marketing of Nexium. Further, unlike Glaxo (*see id.* at 942), AstraZeneca actually performed comparative studies – which undercut any claim of Nexium superiority. Plaintiffs thus do not allege violations arising from representations drawn from Nexium's FDA-approved labeling; nor do they insist that AstraZeneca's advertising should have made any FDA-forbidden representation. Rather, as Plaintiffs have already established, the FDA plainly did not approve AstraZeneca's message of superiority over Prilosec.[10] AstraZeneca misrepresented Nexium's performance relative to Prilosec to preserve its PPI market share and profit margins. The Delaware Consumer Fraud Act thus offers no safe harbor for AstraZeneca's unfair and deceptive conduct.

2. Federal law does not preempt Plaintiffs' claims

AstraZeneca also vaguely asserts throughout its brief that the FDCA preempts Plaintiffs' claims. Understandingly, AstraZeneca says little about the standards

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[10] Indeed, the FDA's Medical Review of the Nexium studies recommended that the FDA "not … allow [AstraZeneca] to claim that [Nexium] has any significant clinical advantage over [Prilosec] … because no data in support of such a claim have been submitted." ¶ 69.

governing federal preemption. Federal-preemption jurisprudence applied to the facts of this case demonstrates that the FDCA does not preempt Plaintiffs' claims.

a. AstraZeneca does not overcome the strong presumption against federal preemption of state-law claims regarding health and safety

Any consideration of preemption issues "starts with the assumption that the historic police powers of the States [are] not to be superseded by ... Federal Act unless that [is] the clear and manifest purpose of Congress." *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992). Thus, "the purpose of Congress is the ultimate touchstone of pre-emption analysis." *Id.* (internal quotation marks omitted); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 747 (1985); *Green v. Fund Asset Mgmt., L.P.*, 245 F.3d 214, 223 (3d Cir. 2001). The proper approach to preemption analysis is to reconcile the operation of both statutory schemes with one another rather than holding one completely ousted. *Hi Tech Trans, LLC v. New Jersey*, 382 F.3d 295, 302 (3d Cir. 2004). The party claiming federal preemption bears the burden to establish that federal law preempts the plaintiff's claims. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 255 (1984); *Green*, 254 F.3d at 230.

b. The FDCA neither expressly nor impliedly preempts state-law claims for deceptive advertising of a prescription drug

Federal preemption may be either express or implied. Implied preemption occurs where federal legislation does not expressly preempt state law, but a review of the legislation indicates that (i) Congress intended federal law to occupy a field exclusively, or (ii) state law is in actual conflict with federal law. *Metropolitan Life Ins. Co.*, 471 U.S. at 738; *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995); *St. Thomas - St. John Hotel & Tourism Ass'n v. Virgin Islands*, 218 F.3d 232, 238 (3d Cir. 2000).

(1) The FDCA does not expressly preempt Plaintiffs' claim

The federal FDCA does not expressly preempt Plaintiffs' state-law claims. Express preemption exists where Congress considered the issue of preemption, included in the legislation a provision expressly addressing that issue, and explicitly provided therein that state law is preempted. *Cipollone*, 505 U.S. at 523. The FDCA contains no such express preemptive language, and not even AstraZeneca suggests otherwise.

(2) The FDCA does not impliedly preempt Plaintiffs' claims – conflict preemption

(a) AstraZeneca must establish an actual, as opposed to a potential, conflict

AstraZeneca fares no better under implied-preemption principles, whether "conflict" or "field" preemption. AstraZeneca bears a heavy burden in establishing conflict preemption. Courts find implied or "conflict" preemption "where it is '***impossible*** for a private party to comply with both state and federal requirements,' … or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Geier v. American Honda Motor Co.*, 529 U.S. 861, 899 (2000) (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (emphasis added); *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373 (2000); *Silkwood*, 464 U.S. at 248. The analysis is the same under either prong[11]: the defendant must demonstrate an ***actual, existing conflict*** – as opposed to a potential, future conflict – between state and federal laws or regulations. *Geier*, 529 U.S. at 884 (conflict preemption "turns on the identification of 'actual conflict'"); *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990) ("state law is pre-empted to the extent that it actually conflicts with federal law"); *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) ("[t]he existence

[11] "We see no grounds, then, for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case." *Geier*, 529 U.S. at 874.

of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute.").

The Supreme Court also instructs courts that any "actual conflict" must be "irreconcilable," *id.*, and consequential. *See also Silkwood*, 464 U.S. at 256. Such "[c]onflicts ... should be of substance and not merely trivial or insubstantial." *New York State Dept. of Soc. Servs. v. Dublino*, 413 U.S. 405, 423 n.29 (1973); *Abdullah v. American Airlines, Inc.*, 181 F.3d 363, 375 (3d Cir. 1999); *Kargman v. Sullivan*, 552 F.2d 2, 12 (1st Cir. 1977). Preemption will not be implied where only a future, potential conflict is asserted. *Otter Tail Power Co. v. United States*, 410 U.S. 366, 377 (1973) ("[a]t present, there is only a potential conflict, not a present concrete case or controversy concerning it").

(b) No actual conflict exists between Plaintiffs' claims and FDA-approved labeling

Plaintiffs' deceptive- and unfair-practices claims arising from AstraZeneca's advertising and promotion practices for Nexium are not conflict preempted because they pose no actual conflict with the FDA-approved labeling. AstraZeneca nonetheless tries to manufacture a conflict by asserting that the FDA-approved labeling for Nexium governed the same advertising and promotional themes challenged here and that Plaintiffs seek to require changes barred by the labeling and FDA rules. Def. Br. at 16-21. But AstraZeneca's premise is incorrect. The FDA's approval of prescription-drug labeling does not reach economic scams of the sort AstraZeneca engineered here, nor did it support any claim of Nexium superiority. The FDA's approval of the Nexium labeling does not permit AstraZeneca to foist Nexium on consumers "as a new, superior drug to Prilosec." Nor do Plaintiffs ask the Court to require AstraZeneca to change its labeling.

As established above, the FDA and FDCA protect the public's health, not its dollars. *See supra* at 10-11. For the same reasons that the DCFA's safe-harbor provision

does not compel dismissal, Plaintiffs' claims do not raise any actual, existing, and irreconcilable conflict with the FDA's approval of Nexium labeling. *See supra* at 11-14.

Moreover, Plaintiffs' unfair competition claims are distinguishable from claims under the FDCA. The FDCA and the state CPA serve different functions: The primary objective of the FDCA is protecting public health. *United States v. Bacto-Unidisk*, 394 U.S. at 798; *Sandoz Pharms. Corp.*, 902 F.2d at 230; *National Nutritional Foods Asso. v. Kennedy*, 572 F.2d at 391; *Zenith Labs., Inc. v. Abbott Labs.*, 1996 U.S. Dist. Lexis 22567, at *13. State laws that regulate competition in the marketplace do not interfere with that goal. *Id.*[12] Courts thus readily distinguish FDCA claims from claims that regulate business practices and competition in the marketplace. In *Zenith Labs.*, for example, a generic drug producer sued the defendant pioneer drug producer relating to its violating a FDCA procedure governing the relationship between pioneer drugs and the generic equivalents. 1996 U.S. Dist. Lexis 22567, at *2-4. The court found no conflict preemption: "the state laws that regulate competition in the marketplace and the FFDCA are not in conflict and easily coexist." *Id.*, at *13. The FDCA's goal is "the protection of public health" whereas the state-law claims at issue "address wrongful business practices," which "are not in conflict and easily coexist." *Id.* (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

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[12] Cases throughout the country have held that federal statutes do not preempt state consumer-protection claims unless they are inconsistent with federal law. *See, e.g., Hinds v. Paul's Auto Werkstatt, Inc.*, 810 P.2d 874 (Ore. 1991) (claims under Oregon's consumer protection statute are not preempted by applicable Federal Trade Commission rule regarding disclosure of defects with used cars); *Mario's Butcher Shop & Food Ctr., Inc. v. Armour & Co.*, 574 F. Supp. 653 (N.D. Ill. 1983) (state consumer protection claims are not preempted where Federal Meat Inspection Act does not provide private cause of action); *Washington Mut. Bank v. Superior Court*, 89 Cal. Rptr. 2d 560 (Cal. App. Ct. 1999) (federal disclosure law that does not provide private cause of action does not preempt state law actions; the state claims compliment, are not inconsistent with, and will promote compliance with federal Real Estate Settlement Procedures Act); *Woolridge v. Redman Homes, Inc.*, 792 F. Supp. 1469 (N.D. Tex. 1991) (state consumer protection claims based on violation of federal regulatory standards are not preempted by the National Manufactured Housing Construction & Safety Standards Act); *McCarthy v. PaineWebber, Inc.*, 618 F. Supp. 933 (N.D. Ill. 1985) (federal Commodity Exchange Act does not preempt state consumer claims where state claims are not inconsistent with federal act).

Recently, the court in *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 885-86 (E.D. Tex. 2005), rejected a similar claim that warnings imposed under state tort law would conflict with the FDA's request that the labeling be exactly as approved. Noting that numerous courts regard FDA labels as a minimum and that additional warnings or information can be required under state law without conflicting with the FDCA, *Cartwright* concluded that the FDCA does not preempt state-law failure-to-warn claims. *Id.* at 882-84 (also discussing cases rejecting preemption). *See also Mylan Labs., Inc.*, 7 F.3d at 1139 (no conflict between FDCA and Lanham Act claims for false and misleading advertising statements of FDA approval); *Solvay Pharms., Inc.*, 298 F. Supp. 2d at 883-85 (same re state and Lanham Act claims for falsely marketing drug as bioequivalent to innovator drug and approved generic equivalents).

Moreover, AstraZeneca's arguments that a conflict might exist arising from its speculations about how it might respond to a damages award in this litigation fail. As already established, conflict preemption requires a finding of a substantial, existing, clear and irreconcilable conflict. *See supra* at 16. The Supreme Court has admonished courts against "seeking out conflicts between state and federal regulation where none clearly exists." *English*, 496 U.S. at 90 (quoting *Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 446 (1960)). *See also Barber v. Hawaii*, 42 F.3d 1185, 1189 (9th Cir. 1994).

AstraZeneca's arguments constitute this very type of a beat-the-bushes search for a potential conflict. It argues that Plaintiffs cannot challenge the FDA's approval of a 40 mg dose of Nexium or AstraZeneca's use of direct-to-consumer advertising because such claims would conflict with FDA actions. But Plaintiffs do not assert such claims. AstraZeneca also insists that Plaintiffs ask the Court to require a disclaimer that a double dose of Prilosec is equally effective as Nexium, and that this disclaimer would conflict with FDA regulations. But Plaintiffs seek no such disclaimer. Plaintiffs ask for a monetary recovery, whether measured by damages, restitution and/or disgorgement.

Complaint at p. 74 (D.I. 20). To the extent Plaintiffs also seek injunctive relief, they will not request relief that would be contrary to FDA regulations.

(3) Nor does the FDCA impliedly preempt Plaintiffs' claims – field preemption

Nor are Plaintiffs' claims impliedly preempted. A state law is "field" preempted if federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the states to supplement it. *Cipollone*, 505 U.S. at 516; *Hi Tech Trans*, 382 F.3d at 303; *St. Thomas - St. John Hotel & Tourism Ass'n*, 218 F.3d at 238. Where federal law touches upon matters historically committed to the police powers of the states, preemption will be found ***only*** if "that was the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485-86 (1996); *California v. ARC Am. Corp.*, 490 U.S. 93, 101 (1989) ("*ARC*"); *Green*, 254 F.3d at 224. Laws concerning unfair business practices are included within the states' police power and thus subject to this heightened presumption against preemption. *ARC*, 490 U.S. at 101; *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 159 (1963). Likewise, regulating medicine and its associated costs is traditionally a state concern. *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997); *Zahl v. Harper*, 282 F.3d 204, 210-11 (3d Cir. 2002). And thus, federal law does not supersede such state laws and claims arising thereunder unless that is the "clear and manifest purpose" of Congress. *E.g.*, *Medtronic*, 518 U.S. at 485. *See also Green*, 245 F.3d at 224-28.

Other courts – including the U.S. Supreme Court – recognize that Congress evidenced an intent that the FDCA ***not*** preempt or displace related state-law claims. In *Medtronic*, the U.S. Supreme Court deemed "implausible" the argument that Congress meant to effectively preclude state courts from offering state consumers any protection from injuries resulting from a defective device under the Medical Device Amendments

Act of 1976, 21 U.S.C. § 360k(a). The court noted that because Congress did not provide a private cause of action in the federal law, to find preemption of state law causes of action would "have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation ...." *Medtronic*, 518 U.S. at 487. The Court found it "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct ...." *Id.* (citation omitted). *Medtronic* thus held that the federal law did not preempt private state law causes of action despite Congress' decision not to provide for private rights of action. *Id. See also, e.g., Consumer Justice Ctr. v. Olympian Labs, Inc.,* 121 Cal. Rptr. 2d 749, 755 (Cal. App. Ct. 2002) ("As far as the [FDCA] is concerned, it would be more accurate to say the act evidences, far from implied preemption, an instance of implied ***non*** preemption. Congress wrote a specific preemption provision for medical devices in the Food, Drug, and Cosmetic Act. (21 U.S.C. § 360k(a).) The obvious implication is that ***no preemption was intended for other items covered by the Act.***") (citation omitted; emphasis added).

The court in *Consumer Justice Ctr.* concluded, "the policy choice by Congress not to allow private causes of action leaves a considerable amount of room left for the states to occupy." *Id.* It next found the nature of plaintiffs' claim – deceptive advertising – was determinative because these claims are readily distinguishable from FDCA labeling and enforcement claims:

> This litigation is not about whether the defendants' products crossed the line from being supplements to being drugs. The plaintiff here is not suing to subject Medi-Phen or Herp-Eeze to the FDA premarket approval process, ***but to stop what it claims is the false advertising of those products*** as safe and effective. There is a difference between the FDA's premarket gauntlet and state litigation which tests the veracity of claims made on behalf of products already on the market. [*Id.* at 756 (emphasis added).]

The court rejected the very argument that Defendant asserts here – that plaintiffs' deceptive-advertising claims tread on matters exclusively within the FDCA's preview:

> The underlying assumption [of defendants' briefing] is that this lawsuit is somehow an attempt to use state unfair competition laws to enforce ***federal*** laws. No, the lawsuit is about state unfair advertising laws. [*Id.* at 758 n.17 (emphasis in original).]

A federal court in *In re Paxil Litig.*, 2002 U.S. Dist. Lexis 24621 (C.D. Cal. Oct. 16, 2002), similarly reasoned that the FDCA did not preempt private state deceptive-advertising claims. Plaintiffs there asserted a deceptive-advertising claim challenging the defendant drug company's advertising claim that its prescription drug was "not habit forming." *Id.*, at *2. The defendant urged dismissal on the preemption theory that "control and regulation of these advertisements are within FDA's exclusive domain." *Id.*, at *3. The court disagreed. First, ***all*** relevant authorities were contrary. *Id.* (citing cases). The court next looked to the FDCA's purpose of "protecting the public," and found that defendants invited the court to find that to further this purpose, Congress not only declined to provide a private cause of action, but also eliminated all common-law state actions. This, the court concluded, "contravenes common sense." *Id.*, at *4 (citing *Medtronic*, 518 U.S. at 487). *See also Morelli v. Weider Nutrition Group, Inc.*, 712 N.Y.S.2d 551, 552 (1st Dep't 2000) (holding that federal labeling regulations under Section 403(q) of the FDCA, 21 U.S.C. § 343(q) did not preempt state consumer-protection claims for deceptive nutritional claims regarding defendants' sports bar).

There can be no doubt under these authorities that Congress did not intend to preempt state-law deceptive-advertising claims. The FDCA's § 337 (21 U.S.C. § 337) does not preempt private state-law claims for deceptive advertising. Plaintiffs allege that AstraZeneca's conduct deceived consumers, and their DCFA claim thus seeks to "vindicate [their] rights under the [DCFA] independent of" the FDCA. *Cf.*, *Cottrell, Ltd.*

v. Biotrol Int'l, Inc., 191 F.3d 1248, 1254 (10th Cir. 1999). Plaintiffs accordingly state a DCFA claim and the FDCA does not preempt it.

B. The First Amendment Does Not Protect AstraZeneca's Deceptive Advertising

1. AstraZeneca's inherently misleading marketing campaign enjoys no First Amendment protection

AstraZeneca's marketing scheme is false, deceptive and misleading. It is therefore not entitled to First Amendment protection. *See Friedman v. Rogers*, 440 U.S. 1, 11 (1979); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 434 (1993) (Blackmun, J., concurring); *In re Warfarin Sodium Antitrust Litig.*, 1998 U.S. Dist. Lexis 19555, at *46-47 (D. Del. Dec. 7, 1998), *rev'd in part on other grounds*, 214 F.3d 395 (3d Cir. 2000). AstraZeneca claims it is entitled to First Amendment protection because its marketing efforts were not inherently misleading, but only "potentially misleading" by implication. Def. Br. at 27. But according to the Supreme Court, "[t]he government may ban forms of communication more likely to deceive the public than to inform it ...." *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 563 (1980) (citing *Friedman*, 440 U.S. at 11, and *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 455-56 (1978)). The Court has also found that a constitutional presumption exists that favors disclosure of information over concealment because disclosure best serves the public interest. *Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 110-11 (1990).

In order to dismiss Plaintiffs' claims on First Amendment grounds on a motion to dismiss, this Court would need to reach a clear determination that Defendant's Nexium promotion was truthful or non-misleading commercial speech. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 504 (1996); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 793 (3d Cir. 1999) (a finding that defendant knowingly withheld facts and falsely represented information created a factual dispute regarding whether

speech was misleading). But the Complaint charts AstraZeneca's repeated use of deception and misrepresentation of material facts in connection with the sale and advertising of Nexium; including misleading statements that Nexium was more powerful and offered significant improvements over Prilosec; and the promotion of Nexium's improved formula, when in reality no difference existed. ¶¶ 53-74, 76, 79; *supra* at 7-8. Plaintiffs also allege that AstraZeneca intentionally promoted Nexium directly to consumers, who are less sophisticated, without disclosing the true comparisons between Nexium and Prilosec. *Id.* Accepting all of the facts in Plaintiffs' Complaint as true, as must be done on this motion to dismiss, AstraZeneca's Nexium campaign was misleading and therefore not entitled to First Amendment protection.

AstraZeneca contends that the First Amendment protects its advertisements because: (i) advertisements that omit facts are not "inherently misleading" *Western States Med. Ctr. v. Shalala*, 69 F. Supp. 2d 1288, 1299-1300 (D. Nev. 1999); and (ii) its advertising is consistent with its federally approved labeling. Def. Br. at 28. Both argument fail.

a. AstraZeneca's Nexium campaign stretches far beyond an omission of facts

AstraZeneca's reliance on *Western States* and *Texans Against Censorship v. State Bar*, 888 F. Supp. 1328 (E.D. Tex. 1995) is misplaced. The courts in those cases found the speech not to be inherently misleading because: (i) they were not actually false; (ii) a less restrictive alternative to a complete ban was available; and (iii) there was no evidence they misled consumers. Specifically, the *Western States* court held that the speech was not "inherently misleading" because there was no evidence that the statements were actually false, and the use of a disclaimer, as opposed to a complete ban, would cure any misconception. 69 F. Supp. 2d at 1299-1300. Similarly, the district court in *Texans Against Censorship*, concluded there was "no evidence, other than conclusory

assertions ... to show that inclusion of the [statement] banned by this rule would actually mislead consumers." 888 F. Supp at 1361. Here, however, Plaintiffs have presented detailed allegations that AstraZeneca's scheme was false and misleading, and that the public was actually deceived. *See* ¶¶ 104-10, 160; *supra* at 7-8.

b. AstraZeneca's second argument fails because Plaintiffs' claims do not arise from Nexium's FDA label

AstraZeneca argues that its advertisements are not inherently misleading because the Complaint fails to establish that Nexium's advertisements are inconsistent with its federally approved labeling. Def. Br. at 28. AstraZeneca, again, misstates Plaintiffs' claims because, again, they do not arise from the FDA-approved Nexium labeling. *See supra* at 9-14.

Defendant's reliance on *Bioganic Safety Brands, Inc. v. Ament*, 174 F. Supp. 2d 1168, 1180-82 (D. Colo. 2001), to support its argument is misplaced. The court in *Bioganic* found, similar to *Western States* and *Texans Against Censorship*, that there was no evidence that the label actually misled anyone and that any misleading impression left by the label could be cured by a less restrictive disclaimer. *Id.* at 1180-82. But here, as already noted, the Complaint alleges both elements the *Bioganic* court found to be absent: (i) AstraZeneca's Nexium scheme actually misled consumers, as evidenced by sales of $3.3 billion by 2003 compared to the waning sales of Prilosec; and (ii) a less restrictive alternative is not available because Plaintiffs' harm already occurred.

And *Cytyc Corp. v. Neuromedical Sys.*, 12 F. Supp. 2d 296 (S.D. N.Y. 1998), which AstraZeneca cites (Def. Br. at 28), actually supports Plaintiffs' position. In evaluating the defendant's motion to dismiss, the *Cytyc* court held that "statements approved as accurate by the FDA [could not] supply the basis for [the] claims." *Id.* at 301. The court ultimately found, however, that many of the defendant's statements were beyond the scope of FDA approval, and therefore, subject to the plaintiff's claims. *Id.*

Nearly the identical scenario exists here. As in *Cytyc*, AstraZeneca's messages about Nexium's superiority are beyond the scope of FDA approval, and therefore, subject to Plaintiffs' claims.

Finally, *Peel*, does not help AstraZeneca. In fact, Defendant's own brief points out that in *Peel* the advertising at issue was "not actually misleading" and based on the "possibility of misleading some consumers." *See* Def. Br. at 29. Here, the Complaint does not articulate some "possibility" of misconceptions about Nexium; it demonstrates the reality of AstraZeneca's efforts, which succeeded in misleading consumers and physicians to use Nexium at a cost of billions of dollars. *Peel* also noted that the mere potential to mislead does not justify the categorical prohibition against the dissemination of accurate factual information to the public. But AstraZenenca's Nexium campaign foisted false information on the public and, therefore, unlike in *Peel*, is not entitled to First Amendment protection.

Because the Company's Nexium scheme is misleading and actually misled consumers, the Company is not entitled to the protections of the First Amendment and, therefore, its motion should be denied.

c. *Noerr-Pennington* immunity does not protect AstraZeneca's inherently misleading marketing campaign

Noerr-Pennington immunity is not applicable here. *Noerr-Pennington* immunity is used specifically to limit the antitrust laws by insuring that private activities that are aimed at influencing the government, including petitioning and litigation are immune from prosecution. *Eastern R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 145 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 669 (1965). Defendant argues that its conduct in obtaining FDA approval is "specifically and absolutely protected by the *Noerr-Pennington* doctrine … [and that] Plaintiffs may not use the courts to litigate the validity of the studies … submitted to the FDA …." Def. Br.

at 26-27. But this is yet another straw-man argument. Plaintiffs' claims are not related to AstraZeneca's activity in obtaining FDA approval. Rather, Plaintiffs' harm stems directly from the Company's systematic false and misleading statements promoting Nexium.

AstraZeneca also incorrectly presumes that the FDA's approval of Nexium labeling immunizes its marketing campaign from any private claim. Def. Br. at 26, 27. But Plaintiffs do not make any claim arising from the Nexium labeling, including that Nexium is ineffective at the FDA-approved dose. Plaintiffs' claims instead target AstraZeneca's intentionally misleading marketing campaign wherein it positioned Nexium as more powerful than Prilosec to instill brand loyalty among consumers and physicians before Prilosec's patent expiration. ¶¶ 92, 103, 155(c). *Noerr-Pennington* is inapplicable to Plaintiffs' claims.

Even if this Court found that *Noerr-Pennington* somehow applied, however, AstraZeneca's marketing efforts would still not be subject to its protection because the Company's statements to consumers were not "incidental to a valid effort to influence governmental action." *Allied Tube & Conduit Corp. v. Indian Head*, 486 U.S. 492, 499 (1988). This Court, in a nearly identical scenario in *In re Warfarin Sodium Antitrust Litig.*, 1998 U.S. Dist. Lexis 19555, at *32, expressly denied the defendant's motion to dismiss based on *Noerr-Pennington* immunity because its statements to the general public and health care community were not "part and parcel" of efforts to secure government regulation. This Court found that based on the alleged use of false reports, combined with public statements impugning the quality of the generic product, it could not infer that "the totality of [the] [d]efendant's public statements were part and parcel of its efforts to secure more stringent [government regulations] ...." *Id.*

As in *Warfarin Sodium*, AstraZeneca's Nexium marketing efforts are not "part and parcel" of any effort to influence public officials, or secure government regulation.

In fact, unlike in *Warfarin Sodium*, AstraZeneca's "new purple pill" scheme is not even arguably ancillary to any effort to influence or achieve government regulation. AstraZeneca's misleading public statements about Nexium's superiority over its own Prilosec sought only to encourage physicians and consumers to switch to the more expensive, branded medication, before Prilosec's patent expired.[13] ¶ 47, 103. *Noerr-Pennington* immunity is thus inapplicable to Plaintiffs' claims and, as such, Defendant's motion should be denied.

2. Plaintiffs do not seek a disclosure from AstraZeneca and therefore their request for injunctive relief is properly pled

Plaintiffs' request for "appropriate injunctive relief" does not specify any particular disclosure from AstraZeneca. Complaint at 74. It is thus premature to even engage in a "compelled speech analysis," and, in any event, such an analysis would not warrant dismissal of plaintiffs' damage claims.

Further, there is no prohibition on compelling correction of false or misleading information. Plaintiffs' Complaint seeks to remedy consumer harm caused by AstraZeneca's inherently misleading Nexium scheme and enjoin AstraZeneca from continuing to falsely promote Nexium as "superior" to its own generic alternative, Prilosec. ¶ 155(a)-(o).

AstraZeneca cites *Pacific Gas & Elec. Co. v. Public Util. Comm'n of Calif.*, 475 U.S. 1, 15 (1986), to support its argument that commercial entities can communicate "whatever truthful, nonmisleading information they wish to communicate." Def. Br. at 30. Perhaps so, but Plaintiffs' Complaint unequivocally alleges that AstraZeneca's Nexium scheme was untruthful and misleading. Therefore, under *Pacific Gas*,

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[13] Defendant argues in footnote 20 of its Opening Brief that "*Noerr-Pennington* also bars Plaintiffs' challenge to [its] (successful) defense of its Prilosec patents against manufacturers of generic omeprazole." Plaintiffs do not challenge the validity of Defendant's Prilosec patents, and Plaintiffs hence do not discuss the applicability of *Noerr-Pennington* to those patents.

AstraZeneca's speech would not be afforded First Amendment protection because it is not "truthful, nonmisleading" speech. In fact, AstraZeneca's motion concedes, as it must, that the State can regulate the use of deliberate deception in advertising. Def. Br. at 30 (citing *Riley v. National Fed'n of the Blind*, 487 U.S. 781, 803 (1988) (Scalia, J., concurring in part and concurring in the judgment)).

AstraZeneca also argues that the possibility that advertisements could mislead some consumers about the relative merits of Nexium and Prilosec would not justify restrictions to its advertising. Def. Br. at 29. Plaintiffs are not attempting to restrict AstraZeneca's advertising of Nexium. The Complaint seeks only to cure the inequities from AstraZeneca's false and misleading Nexium campaign, and enjoin AstraZeneca from continuing to falsely promote Nexium. ¶ 155(a)-(o). AstraZeneca cites *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002), to support its position that banning Nexium advertisements is not the least restrictive means. Def. Br. at 29. As with most of AstraZeneca's cited precedent, *Thompson* is distinguishable for involving a government restriction on the dissemination of truthful speech. 535 U.S. at 374. Here, Plaintiffs claim that AstraZeneca's marketing scheme was inherently misleading and untruthful, and therefore not entitled to First Amendment protection.

Plaintiffs request for injunctive relief, therefore, is properly pled and AstraZeneca's motion should be denied. In any event, the compelled speed issue has no impact on the damage aspect of each of Plaintiffs' claims.

C. Plaintiffs Have Standing

Section III of AstraZeneca's brief takes a shotgun approach at challenging Plaintiffs' standing to bring suit. Despite their many arguments, AstraZeneca consistently misses the mark. *Interfaith Cmty. Org. v. Honeywell Int'l, Inc.*, 399 F.3d 248, 254-55 (3d Cir. 2005) sets forth the minimum requirements for standing: a "concrete" injury. a causal connection between the injury and the conduct complained of,

and a substantial likelihood that the requested relief will remedy the alleged injury. Plaintiffs meet this standard and adequately plead their claims.

1. The Individual Plaintiffs have standing

AstraZeneca first argues that the Individual Plaintiffs have not alleged "the essential elements of economic loss." Curiously, it cites to *City of Pittsburgh v. West Penn Power Comp.*, 147 F.3d 256 (3d Cir. 1998), which has nothing to do with determining whether consumers who have suffered economic losses have standing to assert claims. Another Third Circuit case, however, *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395 (3d Cir. 2003), is far more instructive in that regard. Indeed, the parallels between this case and *Warfarin Sodium* are striking.

Like AstraZeneca, the *Warfarin Sodium* defendant, DuPont Pharmaceuticals, was "anticipating a loss of market share resulting from the introduction of a cheaper generic substitute" for its brand-name product, Coumadin. 214 F.3d at 397. Like here, DuPont "orchestrated a campaign" that included the "publication and dissemination of false and misleading information" to the public and "feeding misinformation to doctors and other medical professionals," all in an effort to differentiate its brand-name product from a competing equivalent product. *Id.*[14] And like here, the pertinent issue was whether the individual purchasers who sued DuPont were injured.

The Third Circuit was unequivocal in ruling that the individual purchaser plaintiffs did allege injury-in-fact:

> Coumadin purchasers ***were the target*** of DuPont's antitrust violation .... The excess amount paid by Coumadin users not only is inextricably intertwined with the injury DuPont aimed to inflict, ***the overcharge was the aim of DuPont's preclusive conduct. It is difficult to imagine a more formidable demonstration of antitrust injury.***

[14] *Compare id. with, e.g.*, ¶¶ 92-97, 104, 125, 146.

Id. at 401 (emphasis added; internal quotes omitted). The Complaint here likewise details a formidable demonstration of consumer injury. Nexium purchasers, including consumers and third-party payors, are the "target" of AstraZeneca's deception because overcharging for Nexium was and is the aim of its marketing campaign. *See, e.g.*, ¶ 110 ("AstraZeneca's Nexium promotional and advertising campaign has resulted in billions of dollars of unnecessary drug expenditures"); ¶ 117 ("The end result is that prescribers and consumers clearly act differently than they otherwise would in the absence of AstraZeneca's false and misleading marketing campaign – they [prescribe] and purchase Nexium when a cheaper, clinically equivalent alternative product is available"); ¶ 146 ("The net effect of this misleading campaign was to establish Nexium in the minds of doctors and consumers as a superior drug for acid relief and as such to allow it to command a price substantially in excess of generic Prilosec").[15]

Ignoring this authority, AstraZeneca instead cites four inapposite cases, none of which involves theories of liability comparable to this case or *Warfarin Sodium*.[16] *Rivera* and *Williams* could each fairly be described as "a product liability suit in which the plaintiffs fail to allege any physical injury." *Williams*, 297 F. Supp. 2d at 176 (internal quotes omitted). In each case, the individual purchaser plaintiffs sought unspecified damages because ***other consumers*** who ingested the drugs at issue were either injured or

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[15] AstraZeneca's deception, however, is much more sophisticated than DuPont's. DuPont affirmatively disparaged generic substitutes for Coumadin; this prompted lawsuits not only by consumers, but also by rival generic drug maker Barr Laboratories, which had a competing warfarin sodium product that DuPont had targeted in its campaign. 214 F.3d at 397. Here, by contrast, AstraZeneca sought to protect its PPI market share by artificially elevating the comparative efficacy of Nexium over Prilosec, thus encouraging physicians and consumers to migrate from Prilosec to Nexium. Because Prilosec was AstraZeneca's own product, a misleading marketing campaign at Prilosec's expense would not draw the ire of Prilosec's manufacturer. Despite these differences the core allegations are similar – a pharmaceutical company is alleged to have made false and misleading statements designed to set its product apart from others so that it could charge higher prices for it.

[16] *See* Def. Br. at 32-33 (citing *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171 (D.D.C. 2003) ("*Williams*"); *Heindel v. Pfizer Inc.*, 2004 WL 1398024 (D.N.J. 2004) ("*Heindel*"); *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174 (N.J. Super. 2003) ("*NJCA*"), and; *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315 (5th Cir. 2002) ("*Rivera*")).